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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KILYK & BOWERSOX, P.L.L.C.
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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

8

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,495

Applicant(s)

SOMACK ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 20-47 and 51-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-19 and 48-50 in Paper No. 7 is acknowledged.
2. Claims 20-47 and 51-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Information Disclosure Statement

3. The information disclosure statement filed 30 Jan. 2002 has been considered and made of record.

Note references 25-32 were not considered because they were not included with the other references in the application file. The foreign patent document (references 25 and 26) could not be located because the document numbers provided did not provide a document that corresponds to the instant subject matter. Japanese patent documents having a 1998 publication date would begin with the "10" rather than "08".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, "the respective second removable cap" lacks antecedent basis. Note claim 4 depends from claim 1 and claim 1 is silent as to the presence of a second cap.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 6, 7 and 13-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Moulton (US 6,063,282) in view of Krueger (US 3,295,686).

The reference of Moulton discloses a plurality of biological sample purification devices (32), each device comprises a tubular body (42) with a first end and a second end and a species-immobilizing filter (48) held within the tubular body. The disclosed system includes a sealing device (16) having a surface adapted to individually seal each of the first end openings of the plurality of devices (See Figure 1).

Claim 1 differs by reciting that each device includes a removable cap adapted to seal the second end opening.

The reference of Krueger discloses that it is known in the art to provide both the first opening and second opening of a tubular filter device with removable caps (11 and 33) so as to prevent the device from being contaminated during storage and/or prior to being used (See column 2, lines 36-70).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bottom or second ends of the purification devices of the primary reference with removable caps as suggested by the reference of Krueger for the known and expected result of preventing the purification devices from becoming contaminated prior to being used.

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With respect to claims 6 and 7, the filter (48) is positioned at the second end of the device and is spaced at a ratio of greater than or equal to 4:1 with respect to the first and second ends of the device.

With respect to claims 13-15, while the device of the primary reference is employed for the purification of DNA fragments from a sample, the reference is silent as to the source of the sample. However, cell lysates, whole blood and tissue extracts are all known in the art to be sources of nucleic acid samples. As a result, it would have been obvious to one of ordinary skill in the art to employ any well-known source of nucleic acid based merely on the intended sample to be analyzed.

With respect to claim 16, the sealing device (16) seals the first ends of the purification devices during use.

10. Claims 1, 2, 6, 7, 10, 11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bankier et al.(US 5,846,493) in view of Krueger (US 3,295,686) and Sanadi (US 5,741,463).

The reference of Bankier et al. discloses a plurality of biological sample purification devices (50), each device comprises a tubular body (10) with a first end (12) and a second end (42) and a species-immobilizing filter (38) held within the tubular body.

Claim 1 differs by reciting that the system includes a sealing device having a surface to individually seal each of the first openings and that each device includes a removable cap adapted to seal the second opening.

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The reference of Krueger discloses that it is known in the art to provide both the first opening and second opening of a tubular filter device with removable caps (11 and 33) so as to prevent the device from being contaminated during storage and/or prior to being used (See column 2, lines 36-70).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bottom or second ends of the purification devices of the primary reference with removable caps as suggested by the reference of Krueger for the known and expected result of preventing the purification devices from becoming contaminated prior to being used.

While the reference of Krueger suggests sealing the first ends with removable caps, claim 1 requires the use of a sealing device having a surface to individually seal each of the first openings.

The reference of Sanadi discloses a variety of well-known means for sealing the openings of an array of openings of a multi-well plate device. Figure 1 discloses the use of a sealing device (1,2) that has a surface for individually sealing each of the openings.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sealing device as suggested by the reference of Sanadi for the known and expected result of providing a means known in the art for sealing an array of openings. Use of the device of Sanadi would be advantageous because it would eliminate the need for an individual cap for each opening while providing the sealing suggested by the reference of Krueger to prevent contamination of the purification device.

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With respect to claim 2, Figure 4A of Sanadi discloses an alternative-sealing device that includes a plurality of recesses formed by elements (73). In view of this teaching, it would have been obvious to provide recesses as suggested by Sanadi for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing an array of openings.

With respect to claims 6 and 7, the filter (38) is positioned at the second end of the device and is spaced at a ratio of greater than or equal to 4:1 with respect to the first and second ends of the device.

With respect to claims 10 and 11, the filter (38) is disclosed as a nucleic acid purification filter that can bind nucleic acids.

With respect to claims 13-15, while the device of the primary reference is employed for the purification of DNA fragments from a sample, the reference is silent as to the source of the sample. However, cell lysates, whole blood and tissue extracts are all known in the art to be sources of nucleic acid samples. As a result, it would have been obvious to one of ordinary skill in the art to employ any well-known source of nucleic acid based merely on the intended sample to be analyzed.

With respect to claims 16 and 19, the first open ends of the devices would be sealed with the sealing device during storage of the device.

With respect to claims 17 and 18, the use of a sealing device as suggested for the first openings would have been obvious for sealing the second openings of the device in place of the use of removable caps for the known and expected advantages of using a single device to seal a plurality of openings.

11. Claims 3-5, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bankier et al.(US 5,846,493) in view of Krueger (US 3,295,686) and Sanadi (US 5,741,463) further in view of Horton (US 5,112,574).

The combination of the references of Bankier et al., Krueger and Sanadi has been discussed above.

The above claims differ by appearing to recite that the claimed system includes both a sealing device and separate caps for sealing either of the ends of the purification devices.

The reference of Horton discloses that it is known in the art that in an array of devices it may be desirable to use only a single device in the array of devices (See column 1, lines 52-60). To prevent waste of the unused devices in the array, the reference of Horton discloses the use of individual caps that can seal the openings in the array (See column 2, lines 18-31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a sealing device that seals all of the openings and individual caps such that the user of the system has the option of using the sealing device or the caps based merely on the intended use of the device. The use of individual caps would be employed when using less than all of the devices in the array of devices.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bankier et al.(US 5,846,493) in view of Krueger (US 3,295,686) and Sanadi (US 5,741,463) further in view of Nix et al.(US 6,402,950).

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The combination of the references of Bankier et al., Krueger and Sanadi has been discussed above.

The above claims differ by reciting that the sealing device includes an adhesive.

The reference of Nix et al. discloses that it is known in the art to employ an adhesive film or foil to seal the openings of an array of openings in a purification device (See column 8, lines 63-68).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to seal the first openings of the device using an adhesive film for the known and expected result of providing an art recognized equivalent to achieve the same result, protecting the contents of the device during storage.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bankier et al.(US 5,846,493) in view of Krueger (US 3,295,686) and Sanadi (US 5,741,463) further in view of Leying et al.(US 5,955,271) and Sheer et al.(US 5,124,041).

The combination of the references of Bankier et al., Krueger and Sanadi has been discussed above.

The above claims differ by reciting that the system includes a polymerase solution in the purification device.

The reference of Leying et al. discloses that it is well known in the art to purify and amplify nucleic acid in the same vessel (See Example 1).

The reference of Sheer et al. discloses that it is known in the art to perform PCR in situ on the purification media of a device (See column 8, lines 46-47).

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In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system with PCR reagents for the known and expected result of performing PCR on the purified sample in the filter device. As shown in the prior art, in situ PCR is an acceptable alternative to elution of the purified nucleic acid that is amplified in a separate vessel.

14. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernwood et al. (US 5,141,719) in view of Krueger (US 3,295,686).

The reference of Fernwood et al. discloses a plate (11,16) having a first surface and a second surface that opposes the first surface and a plurality of through-holes (12, 41) where each through-hole extend from the first surface to the second surface and define a first opening at the first surface and a second opening at the second surface (See Figure 4). The plate includes a plurality of species-immobilizing filters (13) disposed in each through-hole. The reference discloses that the filter can be a continuous sheet or individual disks (See column 3, lines 12-30).

Claim 48 differs by reciting that the system includes a first sealing device adapted to individually seal each of the first openings and a second sealing device adapted to seal each second end opening. Dependent claim 49 specifies that the first sealing device is a plurality of caps.

The reference of Krueger discloses that it is known in the art to provide both the first opening and second opening of a tubular filter device with removable caps (11 and 33) so as to prevent the device from being contaminated during storage and/or prior to being used (See column 2, lines 36-70).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bottom or second ends of the purification devices of the primary reference with removable caps as suggested by the reference of Krueger for the known and expected result of preventing the purification devices from becoming contaminated prior to being used.

While the reference of Krueger suggests sealing the first ends with removable caps, claim 48 requires the use of a sealing device having a surface to individually seal each of the first openings.

The reference of Sanadi discloses a variety of well-known means for sealing the openings of an array of openings of a multi-well plate device. Figure 1 discloses the use of a sealing device (1,2) that has a surface for individually sealing each of the openings.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sealing device as suggested by the reference of Sanadi for the known and expected result of providing a means known in the art for sealing an array of openings. Use of the device of Sanadi would be advantageous because it would eliminate the need for an individual cap for each opening while providing the sealing suggested by the reference of Krueger to prevent contamination of the purification device.

With respect to claim 50, Figure 4A of Sanadi discloses an alternative-sealing device that includes a plurality of recesses formed by elements (73). In view of this teaching, it would have been obvious to provide recesses as suggested by Sanadi for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing an array of openings.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
June 9, 2003